

Translation

PATENT COOPERATION TREATY

PCT/AT2003/000116



PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference R 41027	<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/AT2003/000116	International filing date (day/month/year) 23 April 2003 (23.04.2003)	Priority date (day/month/year) 25 April 2002 (25.04.2002)
International Patent Classification (IPC) or national classification and IPC A61K 9/70		
Applicant NUTROPIA ERNÄHRUNGSMEDIZINISCHE FORSCHUNGS GMBH		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of <u>4</u> sheets, including this cover sheet.
<input checked="" type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).
These annexes consist of a total of <u>1</u> sheets.
3. This report contains indications relating to the following items:  I <input checked="" type="checkbox"/> Basis of the report II <input type="checkbox"/> Priority III <input type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability IV <input type="checkbox"/> Lack of unity-of invention V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement VI <input type="checkbox"/> Certain documents cited VII <input type="checkbox"/> Certain defects in the international application VIII <input type="checkbox"/> Certain observations on the international application

Date of submission of the demand 14 November 2003 (14.11.2003)	Date of completion of this report 19 April 2004 (19.04.2004)
Name and mailing address of the IPEA/EP	Authorized officer
Facsimile No.	Telephone No.

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/AT2003/000116

## I. Basis of the report

## 1. With regard to the elements of the international application:\*

- ☐ the international application as originally filed
- ☒ the description:  
pages \_\_\_\_\_ 1-21 \_\_\_\_\_, as originally filed  
pages \_\_\_\_\_, filed with the demand  
pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_
- ☒ the claims:  
pages \_\_\_\_\_, as originally filed  
pages \_\_\_\_\_, as amended (together with any statement under Article 19  
pages \_\_\_\_\_, filed with the demand  
pages \_\_\_\_\_ 1-8 \_\_\_\_\_, filed with the letter of \_\_\_\_\_ 07.05.2004
- ☐ the drawings:  
pages \_\_\_\_\_, as originally filed  
pages \_\_\_\_\_, filed with the demand  
pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_
- ☐ the sequence listing part of the description:  
pages \_\_\_\_\_, as originally filed  
pages \_\_\_\_\_, filed with the demand  
pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_

## 2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language \_\_\_\_\_ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

## 3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages \_\_\_\_\_
- ☐ the claims, Nos. \_\_\_\_\_
- ☐ the drawings, sheets/fig \_\_\_\_\_

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).\*\*

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).

\*\* Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/AT 03/00116

## V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

### 1. Statement

Novelty (N)	Claims	1 - 8	YES
	Claims		NO
Inventive step (IS)	Claims	1 - 8	YES
	Claims		NO
Industrial applicability (IA)	Claims	1 - 8	YES
	Claims		NO

### 2. Citations and explanations

Document D1 (XP002247615) describes a diet therapy carried out in the context of a hypoallergenic diet with the addition of a drink consisting of mare's milk for treating allergic dermatosis in children.

Document D2 (XP002247616) discloses the use of pure, natural horse milk by the process of chemical extraction and concentration and the addition of stearic acid, white Vaseline, glycerin, liquid paraffin wax, etc., to obtain the end product, which has therapeutic uses in the healing of dermatitis, sunburn, etc.

The use of highly dispersed silicic acid (such as Aerosil®) as a matrix for numerous active substances was known to a person skilled in the art. See documents D3 (US-A-4559222), D4 (XP009013847), D5 (XP009013852) and D6 (XP00306320).

Document D3 describes mixtures of colloidal silicon dioxide (CSD), mineral oil (MO) and polyisobutylene (PI), which are well-suited for use as a medication-containing matrix in transdermal release systems.

Document D4 discloses silicon dioxide as a matrix for highly dispersed amorphous and metastable crystalline forms of indomethacin.

Document D5 describes the influence on skin surface lipids of a number of local therapeutics such as Aerosil (highly dispersed silicon dioxide), which has been used in many pharmaceutical and cosmetic preparations. It serves as a thickening agent for ointments, as a stabilizer for emulsions and as a carrier substance for many active substances.

Document D6 discloses newer auxiliary agents for the preparation of dermatological and cosmetic products containing silicon dioxides.

However, none of the cited documents discloses or suggests the use of a dried mare's milk concentrate based on a biologically inert, highly dispersed matrix for the purpose of producing a preparation to be taken orally for treating skin diseases, particularly dry skin diseases.